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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 10.23.02

Publication Date 10.24.02

Certifier G. Presley

Food and Drug Administration

Development of Donor Screening Assays for West Nile Virus; Public Workshop

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AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop entitled "Development of Screening Assays for West Nile Virus." The objectives of the workshop are to review current developments in West Nile Virus (WNV) transmission in the United States and to explore strategies to address issues related to the development of donor screening tests and the utility of virus inactivation methods.

Date and Time: The workshop will be held November 4 and 5, 2002, from 8:00 a.m. to approximately 5 p.m. on both days.

Location: The workshop will be held at the Hyatt Regency Bethesda, One Metro Center, Bethesda, MD.

Contact Person: Joseph Wilczek, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6129, FAX 301–827–2843, e-mail: wilczek@cber.fda.gov.

SUPPLEMENTARY INFORMATION: FDA, Office of the Secretary/Office of Public Health and Science, the Centers for Disease Control and Prevention, the National Heart, Lung and Blood Institute at the National Institutes of Health, and the Health Resources Services Administration are co-sponsoring a public workshop to focus on scientific issues related to the development of tests that

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are suitable for screening blood and organ/tissue donors for WNV. The ongoing epidemic of WNV infections has raised concerns that WNV can be transmitted through blood transfusions and organ/tissue donations. Currently, there are no tests available to screen blood and organ/tissue donors for WNV nor are there data available about the stability of WNV in such tissues.

On the first day, the workshop will deal with the topics of WNV pathogenicity and epidemiology, methodologies suitable for screening WNV in blood and organ/tissue donors, and development of WNV screening assays for future large-scale implementation in a donor screening setting. On the second day, it will focus on the prospective studies for establishing the transmission to recipients of blood, or human cells, tissues, and cellular or tissue based products, issues relevant to implementation of WNV tests, FDA's expectation for licensure of WNV tests, and strategies for inactivation.

Registration: Because seating space is limited, we recommend early registration. Mail, fax, or e-mail your registration information (including name, title, firm name, address, telephone, and fax number) to Joseph Wilczek (see *Contact Person*). Registration at the site will be done on a space available basis on the days of the workshop, beginning at 7:30 a.m. There is no registration fee for the workshop. If you need special accommodations due to a disability, please contact Joseph Wilczek at least 7 days in advance.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. In addition, the

transcript will be placed on the FDA Web site at http://www.fda.gov/cber/minutes/workshop-min.htm.

Dated: 10-17-02
October 17, 2002.

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 02–????? Filed ??–??–02; 8:45 am]

BILLING CODE 4160–01–S

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